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Great Falls

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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
GREAT FALLS DIVISION**

.....
TAKEDA PHARMACEUTICALS
AMERICA, INC.; TAKEDA
PHARMACEUTICALS U.S.A.,
INC., f/k/a TAKEDA
PHARMACEUTICALS NORTH
AMERICA, INC.; and TAKEDA
PHARMACEUTICAL COMPANY
LIMITED,

Plaintiffs,

-vs-

VICTOR CONNELLY,

Defendant.
.....

CASE NO. *CV-14-50-GF-Bmm-RKS*

**COMPLAINT FOR INJUNCTIVE
AND DECLARATORY RELIEF**

COME NOW, Plaintiffs Takeda Pharmaceuticals America, Inc.; Takeda
Pharmaceuticals U.S.A., Inc., F/K/A Takeda Pharmaceuticals North America, Inc.;

and Takeda Pharmaceutical Company Limited (collectively “Takeda”) and file this Complaint for Injunctive and Declaratory Relief.

INTRODUCTION

Defendant Connelly is an enrolled member of the Blackfeet Indian tribe, who resides on the Blackfeet Reservation. He obtained the prescription diabetes drug ACTOS® (pioglitazone HCl) (“Actos”), from an Indian Health Service clinic on the Blackfeet Reservation after prescription by an Indian Health Service doctor. He thereafter sued Takeda, the non-member prescription drug manufacturer and marketer, in the Blackfeet tribal court, claiming that the drug injured him. Takeda's activity with regard to Actos did not occur on the Blackfeet Reservation. The tribal court “plainly” lacks jurisdiction over this products liability case. In addition, Connelly's actions in the tribal court are motivated by harassment and bad faith, and comity interests have been fully served. Because jurisdiction is “plainly” lacking and Takeda meets other exceptions to the exhaustion requirement, Takeda need not exhaust tribal court remedies before seeking declaratory relief that the tribal court lacks jurisdiction.

A. PARTIES

1. Plaintiffs Takeda Pharmaceuticals America, Inc. (TPA) and Takeda Pharmaceuticals U.S.A., Inc., F/K/A Takeda Pharmaceuticals North America, Inc. (TPUSA) are Delaware corporations with their principal places of business in Deerfield, Illinois. Plaintiff Takeda Pharmaceutical Company Limited (TPC) is a Japanese corporation with its principal place of business in Osaka, Japan. Pursuant to approval by the United States Food and Drug Administration (FDA), TPUSA markets and TPA sells, markets, and distributes Actos for prescription by licensed physicians in the United States. TPC is the Japanese parent company of TPUSA; pursuant to approval by the FDA, TPC has researched and manufactured Actos. The Takeda plaintiffs are non-members of the Blackfeet Indian Tribe.

2. Defendant Victor Connelly (“Connelly”) is an enrolled member of the Blackfeet Indian Tribe, who resides on the Blackfeet Indian Reservation in Montana.

B. JURISDICTION

3. The United States District Court has jurisdiction over this action because it involves a federal question arising under the laws of the United States and is brought pursuant to 28 U.S.C. § 1331, and presents an actual controversy under 28 U.S.C. § 2201. The issue in this action is whether the Blackfeet Tribal Court has adjudicatory jurisdiction over Connelly’s products liability action against

non-member Takeda arising from his use of the prescription drug he obtained from the federal government's Indian Health Service (IHS). Questions of tribal court authority over non-Indians are matters of federal law, cognizable under 28 U.S.C. §1331. *Natl. Farmers Union Ins. Companies v. Crow Tribe of Indians*, 471 U.S. 845, 852-53 (1985) (“[t]he question whether an Indian tribe retains the power to compel a non-Indian . . . to submit to the civil jurisdiction of a tribal court is one that must be answered by reference to federal law and is a “federal question” under [28 U.S.C.] ¶ 1331.”); *Evans v. Shoshone-Bannock Land Use Policy Comm.*, 736 F.3d 1298, 1302 (9th Cir. 2013) (“Non-Indians may bring a federal common law cause of action under 28 U.S.C. § 1331 to challenge tribal court jurisdiction.”) quoting *Elliott v. White Mountain Apache Tribal Court*, 566 F.3d 842, 846 (9th Cir. 2009). The jurisdiction of the Blackfeet Tribal Court over claims arising from an IHS doctor's prescription of an FDA-approved and regulated prescription drug that non-member Takeda sells throughout the United States is a question of federal law. *Id.*

4. The Court has personal jurisdiction over Defendant Connelly as he is both found and resides within this Blackfeet Indian Reservation located within the State of Montana, Great Falls Division. Ex. 1 (Plaintiff's Original Complaint (“Complaint”), *Victor Connelly v. Takeda Pharmaceuticals America, Inc.; Takeda Pharmaceuticals U.S.A., Inc., F/K/A Takeda Pharmaceuticals North America, Inc.*;

and Takeda Pharmaceutical Company Limited, Tribal No. 2013 CA 140. at ¶ 2.1).

C. VENUE

5. Venue is proper in this District and Division pursuant to 28 U.S.C. 1391(b) because it is the location in which Defendant Connelly resides and in which a substantial part of the events and actions giving rise to this Declaratory Judgment Action occurred. For these reasons, venue also is proper under L.R. 3.2(b), Local Rules of the District of Montana.

D. FACTS

Takeda's Sale of Actos

6. Takeda is one of several manufacturers of pioglitazone, a drug used to treat patients with type 2 diabetes.

7. Under the Food, Drug, and Cosmetic Act (FDCA), a prescription drug may not be marketed and sold in the United States until FDA has approved it. 21 U.S.C. § 355 (a) (1999-2013). The FDA approved Actos on July 15, 1999. Ex. 2 (FDA Approval letter). Beginning in 1999, Takeda, through its subsidiaries, distributed pioglitazone in the United States. FDA approved new Takeda pioglitazone-containing drugs in 2005, 2006, and 2009. Ex. 3 (FDA Approval letters).

Connelly's Lawsuit against Takeda

8. IHS is a federal agency within the Department of Health and Human Services, responsible for providing federal health services to American Indians.¹ IHS provides medical care to Blackfeet Indians at clinics on the Blackfeet Indian Reservation. See Indian Health Service, http://www.ihs.gov/billings/index.cfm?module=bao_su_blackfeet.

9. Beginning in 2005, Defendant Connelly sought medical treatment for his diabetes from the IHS clinic on the Blackfeet Reservation. Ex. 4 (Excerpts from the 6/16/14 Deposition of Dr. Richard Odegaard (“Odegaard Depo.”)) at 9:25 – 10:21, 27:23 – 28:2. Connelly’s IHS doctors prescribed Actos to him. *Id.* at 27:4-7.

10. Connelly had no communications with Takeda about Actos. Ex. 5 (Excerpts from the 12/4/13 Plaintiff’s Answers to Defendants’ First Discovery Request (“Interrogatory Responses”)), Responses to Interrogatories #17, #19, and #20).

11. In 2008, Connelly was diagnosed with bladder cancer by his IHS physician. *Id.* at #21.

¹ The Indian Health Care Improvement Act of 1976 (25 U.S.C 1601, *et seq.*) and the Snyder Act of 1921 (25 U.S.C 13) comprise the basic legislative authority for the Indian Health Service.

12. On August 1, 2013, Connelly filed a products liability against Takeda in the Blackfeet Tribal Court, alleging that Actos caused his bladder cancer. Ex. 1 (Complaint). He alleged that Takeda is liable to him for compensatory and punitive damages under theories of strict products liability, negligence, breach of warranty, and violation of the Blackfeet Consumer Sales Practices Act. *Id.*, at ¶¶4.1 – 11.1.

13. As grounds for jurisdiction in the Blackfeet tribal court, Connelly alleged that Takeda sold and marketed Actos in the United States and worldwide, and “to pharmacies and physicians located on Blackfeet tribal trust land” through IHS. *Id.* at ¶ 1.2. He further alleged that his IHS healthcare providers prescribed Actos to him at the clinic located within the Blackfeet Reservation, and he obtained the drug at the IHS Pharmacy. Finally, he alleged that Takeda “came onto the Reservation, through their representatives and agents,” with intent to have IHS doctors and pharmacies make the drug available to Blackfeet tribal members. *Id.* at ¶2.4.

14. Takeda filed a Motion to Dismiss in the tribal court dated August 30, 2013, alleging that the tribal court lacked jurisdiction over this case. Ex. 6 (Defendants’ Motion to Dismiss). Specifically, Takeda argued that Indian tribal courts have limited jurisdiction over non-members, and that generally the sovereign powers of an Indian tribe do not extend to the activities of nonmembers

of the tribe, subject to narrow exceptions, not present here. *Id.* at p. 5-15. *See Montana v. United States*, 450 U.S. 544, 565 (1981). This is especially true where the conduct at issue *occurred off the Reservation*.

15. The tribal court did not rule on Takeda's Motion to Dismiss, but in November 2013, entered an order setting the case for trial on April 24, 2014. Ex. 7.² Takeda agreed to participate in limited discovery. Pursuant to Connelly's demand, Takeda produced a corporate representative to testify about Connelly's allegation that Takeda employees entered the Blackfeet Reservation to market Actos to IHS doctors there.

16. Connelly deposed Takeda's corporate representative Jeffrey McClellan, on April 25, 2014, in Spokane, Washington. McClellan is Takeda's Elite District Sales Manager for the Pacific Northwest, which included Montana. McClellan's testimony established that no Takeda employees came onto the Blackfeet Indian Reservation for the purpose of selling or promoting Actos:

Q. Did any Takeda sales representative who handled Actos conduct any business, including but to – not limited to any sales activity at the IHS facility hospital, on the Blackfeet Indian Reservation?

A. They did not.

...

Q. Did any Takeda employees who were – who were responsible for Indian Health Services ever conduct any business at the IHS

² The parties thereafter agreed to request moving the trial date to August 2014.

facility on the Blackfeet Indian Reservation?

A. No.

(Ex. 8, Excerpts from the 4/24/14 Deposition of Jeffrey McClellan (“McClellan Depo.”)) at 117:12-118:19). McClellan further testified that Takeda's contacts with IHS regarding the formulary's inclusion of Actos were through the central IHS with its corporate headquarters in Oklahoma City. *Id.* at 24:5-11; 26:10-27:4; 35:6-7; 51:4-8; 80:22-23; .128:8-12.³

17. Takeda also submitted the Declarations of the company sales representatives identified by McClellan who could have had responsibility for contacting healthcare providers in Montana, and each of them confirmed that they never entered the Blackfeet Indian Reservation to discuss Actos. Ex. 9 (Declarations of Gretchen Millard, Matt Sheridan, Darrin Branson, Brian Burns, Donna Bishop, Michael Underhill, Leroy Hucke, Brandon Butler, and Brian Sherle).⁴

18. Additionally seven Takeda employees who had contact with IHS about Actos submitted Declarations affirming that they never went onto the Blackfeet Indian Reservation. Ex. 10 (6/9/14 Defendants' Motion for

³ One of Connelly's prescribing physicians testified that he believed that the clinic made some decisions about what drugs to prescribe, but offered no testimony that Takeda employees came onto the Reservation to market Actos. Ex. 4 (Odegaard Depo.), at 34:17-22; 35:18-20; 65: 19-25; 99:3-17.

⁴ McClellan identified these sales representatives in his deposition. Ex. 8 (McClellan Depo.) at 123:20-124:15.

Reconsideration of Order Compelling Depositions and Supplement to Motion to Quash and for Protective Order, Declarations of Christopher Benecchi, William Engro, Charles Kelly, Harry Hayter, Neil McFadden, Andi Moore, and Mark Oldroyd (“Mot. for Reconsideration”)).

19. The record evidence thus establishes that no Takeda representative or employee ever went onto the Blackfeet Indian Reservation for the purpose of selling or promoting Actos; rather, Takeda representatives interacted with the IHS in Oklahoma City, where the IHS – not the Blackfeet Tribe – decided that IHS would include Actos as a medicine on its federal drug formulary for IHS facilities throughout the United States. Ex. 10 (Mot. for Reconsideration) at p. 4; Ex. 8 (“McClellan Depo.”) at 24:8-11.

20. Connelly then amended his Complaint to allege that the tribal court had jurisdiction because Takeda had contacts with Indian Health Service (in Oklahoma) to market Actos for the formulary, which would have included the Blackfeet Indians. Ex. 11 (Plaintiff’s First Amended Original Complaint (“Am. Complaint”)) at ¶ 2.5. He further claimed that Takeda used “marketing tactics” to “drive Actos business in all IHS facilities.”

21. Takeda filed a Renewed Motion to Dismiss, asserting that this allegation, even if true, would not confer jurisdiction on the tribal court for

Connelly's use of Actos. Ex. 12 (5/14/14 Defendants' Takeda's Renewed Motion to Dismiss) at pp. 7-8. Connelly never responded.

22. Connelly next demanded the depositions of Takeda's General Counsel and Assistant General Counsel and on May 6, 2014, he noticed the depositions of these two lawyers, with Tribal Court subpoenas to produce company documents relating to Takeda's contact with IHS and the Blackfeet Reservation. Ex. 13 (Letter from Jason C. Webster enclosing Deposition Notices and Subpoenas Duces Tecum) at B31-B44.

23. On that same date, Connelly also noticed the depositions of seven other current and former Takeda employees, six of whom worked in Managed Markets, the Takeda division that had contacts with IHS about prescription drugs that the federal government would include on drug formularies for federal health programs. He attached Tribal Court subpoenas for production of documents relating to Takeda's contact with IHS and the Blackfeet Reservation. (*Id.* at B3-B30).

24. Takeda offered Connelly a corporate representative pursuant to Fed. R. Civ. P. 30(b)(6) on the subjects of its contacts with IHS as an alternative to the depositions of Takeda's top lawyers and seven additional employees scattered over the United States. Ex. 14 (5/20/14 Letter). Connelly ignored the offer.

25. When Takeda did not provide deposition dates for its attorneys and the other witnesses, on May 23, 2014, Connelly filed a Motion to Compel their depositions, which Takeda did not receive until four days later. Ex. 15 (Motion to Compel Depositions and Request for Monetary Sanctions Against Defendants).

26. Although tribal law gives a party five (5) days after service to object, *see* Blackfeet Tribal Law and Order Code, Ch. 9, Rule 10-A, the tribal court did not wait for Takeda to respond. Rather, without benefit of Takeda's objections, the tribal court entered an order just four working days later granting the Motion to Compel on May 29, 2014, requiring Takeda to produce its General Counsel and Assistant General Counsel along with the seven other witnesses, by July 2, 2014. Ex. 16. Takeda received this order from the tribal court a week later, on June 5, 2014.

27. In its order, the tribal court noted that it had not yet ruled on the Motion to Dismiss but that the case was going to trial in August.

28. Takeda submitted a Motion for Reconsideration on June 9, 2014, asking the tribal court to consider its response to the Motion to Compel, citing substantial authority that the Rules do not allow a party to depose his opponent's

lawyers except in the most limited of circumstances, none of which are present here.⁵ Ex.10 (Mot. for Reconsideration).

29. Takeda also asked the tribal court to consider the Declarations of the seven Takeda former and current employees whose depositions Connelly sought who, consistent with the McClellan deposition, affirmed that none of them ever went to the Blackfeet Reservation to market Actos. *Id.* at p. 4. Though the tribal court ruled on Connelly's motion to compel just four business days after it was filed, it has yet to rule on Takeda's motion for reconsideration.

30. Likewise, the tribal court has failed to rule on the jurisdictional issue for (10) months.

31. The United States Department of the Interior, Bureau of Indian Affairs (BIA), completed a review of the Blackfeet Tribal Court, and on June 4, 2014, found that the Tribal Court judges and Administrator were hired with invalid

⁵ . The tribal court generally is to follow the Federal Rules of Civil Procedure for discovery. See Tribal Law and Order Code, Ch. 9, Rule 27. The Ninth Circuit uses the test first articulated in the seminal case on attorney depositions, *Shelton v. Am. Motors Corp.*, 805 F.2d 1323, 1327 (8th Cir. 1986): a party seeking to depose his opponent's counsel "must show that 1) the desired information cannot be obtained by any other means; 2) the desired information is relevant and nonprivileged; and 3) the desired information is crucial to the preparation of the case." *Willer v. Las Vegas Valley Water Dist.*, No. 98-15686, 1999 U.S. App. LEXIS 7831, *8-9 (9th Cir. Apr. 19, 1999) citing *Massachusetts Mutual Life Ins. Co. v. Cer.*, 177 F.R.D. 472, 479 (N.D. Cal. 1998) (*Shelton* is generally regarded as the leading case on attorney depositions).

tribal resolutions. Ex. 17 (United States Department of the Interior, Bureau of Indian Affairs Monitoring Report (“BIA Report”)) at p. 7.)⁶

E. Count I—Declaratory Judgment

32. Takeda adopts and incorporates each of the allegations in the preceding paragraphs.

Standard for Declaratory Judgment

33. The Declaratory Judgment Act allows a federal court to “declare the rights and other legal relations” of parties to a “case of actual controversy.” 28 U.S.C. § 2201; *Spokane Indian Tribe v. United States*, 972 F.2d 1090, 1091 (9th Cir. 1992). “Declaratory relief is appropriate (1) when the judgment will serve a useful purpose in clarifying and settling the legal relations in issue, and (2) when it will terminate and afford relief from the uncertainty, insecurity, and controversy giving rise to the proceeding.” *Eureka Fed. Sav. & Loan Assn. v. American Cas. Co.*, 873 F.2d 229, 231 (9th Cir. 1989).

34. A case or controversy is ripe if “the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118,

⁶ The BIA Report and its attachments are unnumbered. A copy of the Report is attached as Ex. 17, and page numbers have been added to the document.

127 (2007) (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)).

35. The doctrine of ripeness is designed “to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements.” *Thomas v. Anchorage Equal Rights Comm’n*, 220 F.3d 1134, 1138 (9th Cir. 2000).

36. Declaratory relief is proper here, because it will clarify and settle the legal relations between Takeda and Connelly, and “terminate and afford relief from the uncertainty, insecurity, and controversy” of the tribal court invalidly exercising jurisdiction over Connelly’s case against Takeda in tribal court.

The Blackfeet Tribal Court Plainly Lacks Jurisdiction Over Connelly’s Suit

37. The Court should grant a Declaratory Judgment that the tribal court lacks jurisdiction over the underlying suit that Connelly has filed against non-member Takeda arising from *activity conducted off the Blackfeet Reservation, i.e.*, from Takeda’s sale of an FDA-approved prescription drug to IHS, a non-member federal governmental agency, that supplied it to the IHS clinic.

The Tribal Court Has no Jurisdiction over a Non-Member’s Activity Off the Reservation.

38. Indian tribal courts have limited jurisdiction over the conduct of nonmembers. *Strate v. A-1 Contractors*, 520 U.S. 438, 445 (1997); *Montana v.*

United States, 450 U.S. 544, 565 (1981). “[A]bsent express authorization by federal statute or treaty, tribal jurisdiction over the conduct of nonmembers exists only in limited circumstances.” *Strate*, 520 U.S. at 445 (citing *Oliphant v. Suquamish Indian Tribe*, 435 U.S. 191 (1978) and *Montana*, 450 U.S. at 565). The Ninth Circuit has held that “[t]ribal jurisdiction over non-members is *highly disfavored* and there exists a *presumption against tribal jurisdiction*. There must exist “express authorization” by federal statute of tribal jurisdiction over the conduct of non-members. *Bugenig v. Hoopa Valley Tribe*, 229 F.3d 1210, 1215, 1217 (9th Cir. 2000) (emphasis added) *rev’d on other grounds*, 266 F.3d 1201 (2001); *Strate*, 520 U.S. at 445. For there to be an express delegation of jurisdiction over non-members, there must be a “clear statement” of express delegation of jurisdiction. *Bugenig*, 229 F.3d at 1218-19.

39. While Indian tribes “retain inherent sovereign power to exercise some forms of civil jurisdiction over non-Indians *on their reservations*,” *Montana*, 450 U.S. at 565 (emphasis added), the operative phrase is “*on their reservation*.” Neither *Montana* nor its progeny purport to allow Indian tribes to exercise civil jurisdiction *over the activities or conduct of non-Indians occurring outside their reservations*. See e.g., *Hornell Brewing Co. v. Rosebud Sioux Tribal Court*, 133 F.3d 1087, 1091 (8th Cir. 1998).

40. Takeda is a non-member of the Blackfeet Tribe. Connelly's claims against Takeda arose from Takeda's marketing and sale of Actos to the IHS, which did not occur on the Blackfeet Reservation. Ex. 8 (McClellan Depo.) at 117:12-118:19); Ex. 9; Ex. 10. Rather, the activity of which Connelly complains occurred in Oklahoma, when Takeda representatives met with IHS, and IHS decided to include Actos on the agency's drug formulary. Thus, the tribal court plainly lacks jurisdiction over Connelly's claims for this non-member activity off the reservation.

41. Further, a tribal court's adjudicative jurisdiction does not exceed its legislative jurisdiction. *Strate*, 520 U.S. at 453. Thus, if a tribe could not legislate the activity, it cannot exercise jurisdiction over the activity. *Id.*

42. The Blackfeet Tribe does not have the ability to legislate or regulate the sale of prescription drugs in the United States; Congress has vested the authority to approval and regulate the sale of prescription drugs in the FDA. *See* ¶7, *supra*. Because the Blackfeet Tribal Court lacks the ability to legislate in the area of prescription drugs, it lacks jurisdiction over Takeda's sale of Actos in the United States.

43. Further, the Blackfeet Tribe does not have the authority to legislate or regulate the IHS's determination of what drugs it will make available for IHS doctors to prescribe to IHS-served Indian patients, or an IHS doctor's decision to

prescribe the medicine. The authority of the IHS to perform the United States' duties under federal treaties and statutes to supply healthcare to Indians is determined solely by the federal government through the IHS. *See* ¶ 8, *supra*.

44. Because the Blackfeet Tribal Court lacks the ability to legislate in the area of the IHS selection of prescription drugs, it plainly lacks jurisdiction over activities that include Takeda's marketing of Actos to the IHS for this additional reason. *Evans*, 736 F.3d 1298, 1302-04 ("The plausibility of tribal court jurisdiction depends on the scope of the Tribe's regulatory authority as a 'tribe's adjudicative jurisdiction does not exceed its legislative jurisdiction.'" citing *Plains Commerce Bank*, 554 U.S. at 330 (quoting *Strate*, 520 U.S. at 453).

The Tribal Court Has no Jurisdiction over a Non-Member's Activity On the Reservation Subject to Narrow Exceptions.

45. Even where the conduct occurs *on the reservation*, tribal courts still have limited jurisdiction over non-members. *Montana*, 450 U.S. at 565. "[T]ribes do not, as a general matter, possess authority over non-Indians who come within their borders" *Plains Commerce Bank*, 554 U.S. at 328, citing *Montana*, 450 U.S. at 565. As the Ninth Circuit held, "[a]s a general rule, tribes do not have jurisdiction, either legislative or adjudicative, over nonmembers and tribal courts are not courts of general jurisdiction." *Evans v. Shoshone-Bannock Land Use*

Policy Comm., 736 F.3d 1298, 1302-03 (9th Cir. 2013), quoting *Philip Morris USA, Inc. v. King Mountain Tobacco Co.*, 569 F.3d 932, 939 (9th Cir. 2009).

46. Even if, contrary to the evidence, Takeda representatives *had* entered the Blackfeet Reservation to market Actos to IHS doctors, the tribal court still would lack jurisdiction over Takeda.

47. A tribe may regulate the activities of nonmembers *on the reservation* only if they enter into consensual relationships with tribal members through commercial dealings or other arrangements, or when the nonmember's conduct on reservation/fee lands threatens or has a direct effect on the political integrity, economic security, or health and welfare of the tribe. *Montana*, 450 U.S. at 566.

48. The United States Supreme Court has construed these *Montana* exceptions narrowly. The Court clarified that “[w]here non-members are concerned, ‘the exercise of tribal power *beyond what is necessary to protect tribal self-government or to control internal relations* is inconsistent with the dependent status of the tribes, and so cannot survive without express congressional delegation.’” *Nevada v. Hicks*, 533 U.S. 353, 259 (2001).

49. Connelly cannot establish the first *Montana* exception, *i.e.*, that his lawsuit against Takeda arises from a consensual relationship on the reservation. Connelly had no relationship with Takeda at all—he received a prescription from his IHS healthcare provider. He conceded that he never had contact with Takeda.

As the Supreme Court stated in rejecting a “consensual relationship” between an Indian tribe and a contractor building on non-fee land located on a reservation, where the dispute is “non-tribal in nature” and did not implicate the terms upon which non-members might conduct business on the reservation, the conduct did not qualify as a “consensual relationship.” *Strate*, 520 U.S. at 457. The Ninth Circuit has held that “consensual relationship” exceptions involve either direct regulation by the tribe of a non-Indian activity on the reservation, or lawsuits between private parties and the tribe or a member arising from an activity on the reservation or contract performed there. *See e.g., Smith v. Salish Kootenai College*, 434 F.3d 1127 (9th Cir. 2006) (non-member plaintiff brought suit in tribal court against tribal entity). Here, as in *Strate*, the claims that Connelly makes are “distinctly non-tribal in nature.” The “health and safety” exception reference in *Montana* has been described as requiring a showing that the activity would “imperil the subsistence of the tribal community” or be “catastrophic” for tribal self-government. *Plains Commerce Bank*, 554 U.S. at 341; *Evans*, 736 F. 3d at 1305-06.

50. Neither can Connelly establish the second *Montana* exception; Takeda's sale of FDA-approved Actos to the federal government's IHS for prescription by IHS doctors to Indians does not impinge on the Blackfeet Tribe's self-government; exercise of jurisdiction over Takeda's sale of Actos is not

“necessary” to protect the Blackfeet Tribe’s self-government on the Blackfeet Reservation or control its internal relations.

51. Neither Takeda's sale of Actos in the United States or sale of Actos to the federal government’s IHS would “imperil the subsistence of the [Blackfeet] tribal community” or be “catastrophic” for the Blackfeet Indians’ tribal self-government, nor does it impinge on the Blackfeet Tribe’s self-government.

52. Tort injuries to an individual Indian tribal member does not have a “direct effect upon the health or welfare of the tribe,” even where the safety of other tribe members could be jeopardized. *Strate*, 520 U.S. at 457. In *Strate*, the tribal court plaintiff argued that issues regarding the safety of the highway on which she was injured affected the “health and safety” of the tribe. The Court rejected this broad interpretation of the *Montana* exception, even though the Court acknowledged that “those who drive carelessly on a reservation endanger all in the vicinity and surely jeopardize the safety of tribal members.” 520 U.S. at 457-458. The Court held that accepting that broad a construction of tribal “health and safety” would “severely shrink the rule.” *Id.* This was not the tribal interest recognized in *Montana*’s exception.

53. Thus, even if Takeda employees had entered the Blackfeet Reservation to conduct sales activities with the IHS clinics, this would not confer jurisdiction upon the tribal court, since such activity neither imperils tribal self-

government nor threatens the survival or “health and safety” of the Blackfoot Tribe within the *Montana* exceptions.

54. There also is no tribal authority to regulate nonmembers’ activities on land “over which the tribe could not assert a landowner’s right to occupy and exclude.” *Nevada*, 533 U.S. at 359. The federal government, not the tribe, regulates the activities of the IHS at the federal agency’s facility. Thus, the tribe cannot regulate the IHS decisions over what medicines to include on its formulary, and the prescription of medicines in its clinics. Further, any Takeda sales activity of FDA-approved prescription drugs to IHS is not an activity that the tribal court can legislate or regulate. Thus, tribal court jurisdiction does not reach these activities. The tribal court plainly lacks jurisdiction here.

Exhaustion of Tribal Remedies is not Required Where Jurisdiction is “Plainly” Lacking

55. In the interest of comity and the federal policy of supporting tribal self-government, a party seeking to overturn a tribal court’s exercise of jurisdiction generally must exhaust tribal remedies first, to give the tribal courts the opportunity to rule. *Nat’l Farmers Union Ins. Cos. v. Crow Tribe of Indians*, 471 U.S. 845, 850-53 (1985); *Elliott v. White Mountain Apache Tribal Court*, 566 F.3d 842, 846 (9th Cir. 2009). There are well-recognized exceptions to the exhaustion

requirement, however, most recently applied by the Ninth Circuit last year in *Evans*, 736 F.3d at 1302:

56. Among other things, exhaustion of tribal court remedies *is not required*:

- When it is “plain” that tribal jurisdiction is lacking, so that exhaustion would serve no purpose other than delay; or
- Where the assertion of tribal court jurisdiction is “motivated by a desire to harass or is conducted in bad faith,” or
- Where exhaustion would be futile because of the lack of adequate opportunity to challenge jurisdiction.

736 F.3d at 1302. Takeda can establish multiple exceptions to the exhaustion requirement, so Takeda need not exhaust tribal court remedies here.

Tribal Court Jurisdiction is “Plainly” Lacking

57. It is “plain” here that the tribal court lacks jurisdiction over non-member Takeda for activity conducted off the Blackfeet Reservation. *See* ¶¶ 38-40, *supra*.

58. Tribal jurisdiction over non-members is highly disfavored and there exists a presumption against tribal jurisdiction. *See* ¶38, *supra*.

59. No court has ever ruled that a tribal court can exercise jurisdiction in these circumstances. Connelly argued to the tribal court that its jurisdiction is co-extensive with the limits of due process, as is that of other properly constituted

state and federal courts. But the Supreme Court and Ninth Circuit have held that Indian tribal courts are courts of *limited* jurisdiction, and have only those powers that have been granted to them by federal law. *See* ¶¶ 41-44, *supra*. No federal statute, treaty, or court decision has granted tribal courts the expansive powers to adjudicate a company's sale of prescription drugs off the reservation or the decisions by a federal agency to make the drug available to medical care providers who administer federal health services.

60. Even if Takeda's employees had come on the Reservation, the tribal court still would lack jurisdiction, because Takeda's sale of FDA-approved prescription drugs to a federal agency is not an activity that the tribal court can legislate or regulate, or that imperils the existence of the tribe. *See* ¶¶ 45-54, *supra*.

61. Exhaustion, therefore, would serve no purpose other than further delay here.

Harassment and Bad Faith

62. Connelly's assertion of tribal court jurisdiction also appears to be motivated by "a desire to harass" and "conducted in bad faith." *Id.* No court has ever adopted such an expansive view of the reach of Indian tribal courts, to have concurrent jurisdiction with state and federal trial courts around the country. Connelly properly could file his products liability action in multiple places—in

Montana state or federal court, in the consolidated Actos cases in Illinois, or in the consolidated federal MDL litigation in the United States District Court for the Western District of Louisiana, *In re Actos (Pioglitazone) Products Liability Litigation*, MDL 2299.

63. While the case has been pending in tribal court, Connelly has requested harassing orders that other courts would be unlikely to enter—in demanding the depositions of Takeda's General Counsel and Assistant General counsel on subjects well within the purview of other employees, and then obtaining an order to compel before Takeda's response to the motion was due under tribal rules. Connelly's actions in seeking orders to depose Takeda's lawyers are not made in good faith, and are abusive and designed to harass and burden Takeda.

64. Connelly offered no basis for seeking to depose Takeda's top lawyers, and the tribal court ignored precedent and denied Takeda basic due process in ruling without giving Takeda an opportunity to object.

65. Connelly's conduct of the case in tribal court indicates that his purpose for pursuing his claims in tribal court may be to harass and burden the company, rather than to legitimately pursue his claims.

Exhaustion would be Futile

66. Further exhaustion would be futile here. Connelly filed suit against Takeda on August 1, 2013. Takeda first moved to dismiss for lack of jurisdiction

on August 30, 2013. The tribal court, while favorably ruling on Connelly's requests for relief, has refused to rule on any motions by Takeda, including its Motion to Dismiss. Meanwhile, the tribal court had indicated it will try this case on the merits in August 2014. It appears that the tribal court is *de facto* assuming jurisdiction over the case while refusing to rule. Takeda has given the tribal court every opportunity to rule, honoring comity, but it should not be required to wait further when the trial court is ignoring that opportunity.

Comity Interests Have Been Served Here

67. If the purpose of requiring exhaustion is to respect comity and the federal policy of supporting tribal self-government by giving the tribal court a "full opportunity" to rule, then those purposes have been served here. The tribal court has had that "full opportunity" to rule for ten (10) months. The court has refused to rule on Takeda's Motion to Dismiss, but is moving the case towards trial without ever finding that it has the authority to do so. Under these circumstances, Takeda has given the court the opportunity to rule, so considerations of comity are fully satisfied. Moreover, the tribal court has no ability to regulate or legislate in the area presented, and thus no comity interest in ruling at all. *See, e.g., Middlemist v. Secretary of United States Dep't of Interior*, 824 F. Supp. 940, 943 (D. Mont. 1993) (federal court must examine the circumstances in the individual case to determine if deference is necessary, in light of the purpose of the exhaustion

requirement) quoting *Stock West Corp. v. Taylor*, 942 F.2d 655,661 (9th Cir. 1991).

Count II.—Preliminary and Permanent Injunction

68. Takeda adopts and incorporates here each of the allegations in the preceding paragraphs.

Standard for Injunctions

69. The purpose of a preliminary injunction is to preserve the relative positions of the parties - the status quo - until a trial on the merits can be conducted. *LGS Architects, Inc. v. Concordia Homes of Nev.*, 434 F.3d 1150, 1158 (9th Cir. 2006) (quoting *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981).

70. To obtain a preliminary injunction, Takeda must establish: 1) that it is likely to succeed on the merits; 2) that it is likely to suffer irreparable harm in the absence of preliminary relief; 3) that the balance of equities tips in its favor; and 4) that an injunction is in the public interest. *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *Herb Reed Enters., LLC v. Fla. Entm't Mgmt.*, 736 F.3d 1239, 1247 (9th Cir. 2013).

71. A party can also satisfy the first and third elements of the test by raising serious questions going to the merits of its case and a balance of hardships that tips sharply in its favor. *Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1134-35 (9th Cir. 2011).

72. The standard that a party seeking a permanent injunction must meet is essentially the same as the standard applicable to preliminary injunctive relief.

Amoco Prod. Co. v. Village of Gambell, 480 U.S. 531, 546 n.12 (1987).

Takeda is Entitled to a Preliminary Injunction

73. Takeda can meet each of the four elements of the *Winter* test, entitling it to an injunction against Connelly pursuing his claims against Takeda in tribal court.

Takeda is Likely to Prevail on the Merits

74. First, Takeda is likely to prevail on the merits of its arguments that the tribal court lacks jurisdiction over Connelly's case. Tribal courts lack jurisdiction over the conduct of non-members where the alleged activity was conducted off the Blackfeet reservation. (See ¶¶38-40, *supra*.) But even if Takeda's employees had come onto the Reservation to speak to IHS doctors about Actos, which the evidence negates, the tribal courts still would lack jurisdiction over Takeda. (See ¶¶45-54, *supra*.) Connelly has no authority to support tribal court jurisdiction here. Thus, Takeda is likely to prevail on its challenge to tribal court jurisdiction.

Takeda Is Likely To Suffer Irreparable Harm Absent Preliminary Relief

75. Takeda is likely to suffer irreparable harm if the tribal court forces this case to trial. The June 4, 2014 BIA Report reflects that, among other serious concerns, the tribal court lacks procedures for protection of confidential documents

and its court personnel lack training. Specifically, the Report states: “Years of confidential records are being stored in the conference room in unlocked files . . . The conference room remains open during the day with access to anyone in the building.” Ex. 17 (BIA Report) at 8-9. The Report further states that the court staff had not implemented improved procedures, and that they are untrained and unqualified, they lack knowledge of the Tribal Code and court procedures, and a number had unfavorable background checks. *Id.* at 9-10. In addition, the BIA found that the Tribal Business Council has significant influence over court activities, resulting in unethical interference and due process violations. *Id.* at 7.

76. Against this backdrop, Takeda has a significant need for adequate procedures to protect against the unlawful dissemination of its highly confidential and sensitive documents and trade secrets that will be at issue in the trial.

77. Montana law defines a “trade secret” as

“information ..., including a formula, pattern, compilation, program, device, method, technique, or process, that: (a) derives independent economic value, actual or potential, from not being generally known to and not being readily ascertainable by proper means by other persons who can obtain economic value from its disclosure or use; and (b) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

Mont. Code Ann. § 30-14-402(4).

78. In conjunction with the Actos products liability litigation pending around the country, Takeda has produced millions of pages of documents

containing its commercially confidential and trade secret information relating to its manufacture and marketing of Actos. These documents could be of commercial value to Takeda's competitors, in their own marketing of pioglitazone or other drugs, as they are “not [] generally known to and . . . readily ascertainable by proper means by other persons who can obtain economic value from its disclosure or use.” *Id.*

79. In each case where Takeda's documents have been made available to litigants, the parties have agreed to a Protective Order protecting and limiting the dissemination of Takeda's trade secret information. *See e.g.*, Ex. 18 (*In re Actos (Pioglitazone) Products Liability Litigation* (W.D. La., MDL No. 2299), 7/30/12 Case Management Order (Doc. No. 1540)); Ex. 19 (*In re Actos Related Cases*, Case No. 11 L 10011, *et al.*, Circuit Court of Cook County, Agreed Stipulated Protective Order of Confidentiality entered March 27, 2012).

80. In Connelly's tribal court suit, the parties stipulated to the entry of the Cook County Protective Order. *See* Ex. 20 (Stipulation and Order Regarding Discovery and Trial Matters) at ¶ 4. As a result, Takeda made available to Connelly confidential trade secret documents produced in the Illinois consolidated litigation, with the assumption that these documents would be protected not only by the parties, *but by the Court and court personnel as well.*

81. Given the BIA findings, Takeda's significant property interests are imperiled. Trying this case in tribal court seriously risks the disclosure of Takeda's commercially sensitive and protected documents, given the lack of adequate procedures and trained personnel to protect its confidential information, and the findings of outside influences over tribal court proceedings.

82. If Takeda's documents are not protected, as might happen in tribal court, Takeda risks the loss of its valuable trade secrets, which cannot be remedied by any monetary judgment. "Public disclosure of a trade secret destroys the information's status as a trade secret." *Saini v. Int'l Game Tech.*, 434 F. Supp. 2d 913, 919 (D. Nev. 2006). "Such destruction causes irreparable harm to the trade secret owner "by both depriving him of a property interest and by allowing his competitors to reproduce his work without an equivalent investment of time and money." *Id.* (citations omitted). Such harms are unlikely to be adequately redressed by monetary damages." *V'Guara Inc. v. Dec*, 925 F. Supp. 2d 1120, 1126 (D. Nev. 2013). Other courts have recognized that a threatened loss of valuable trade secrets may establish irreparable harm. *See e.g., Stuhlberg Int'l Sales Co. v. John D. Brush and Co., Inc.*, 240 F.3d 832, 841 (9th Cir. 2001) ("Evidence of threatened loss of prospective customers or goodwill . . . supports a finding of the possibility of irreparable harm."); *Gallagher Benefit Servs., Inc. v. De La Torre*, 283 Fed. Appx. 543, 546 (9th Cir. Jun. 24, 2008) (affirming district

court's conclusion that injury to goodwill and customers due to trade secret misappropriation constitutes irreparable harm); *Rent—A—Center, Inc. v. Canyon Tele. & Appliance Rental, Inc.*, 944 F.2d 597, 603 (9th Cir.1991) (harm to business goodwill and reputation is unquantifiable and considered irreparable); *TMX Funding, Inc. v. Impero Techs., Inc.*, No. C 10-00202 JF (PVT), 2010 U.S. Dist. LEXIS 37064, 2010 WL 1028254 at *8 (N.D. Cal. Mar. 18, 2010) (stating that "California courts have presumed irreparable harm when proprietary information is misappropriated"); *Lillge v. Verity*, No. C 07-2748, 2007 U.S. Dist. LEXIS 73543 at *20, 2007 WL 2900568 at *7 (N.D. Cal. Oct. 2, 2007) (finding that the "risk of losing established customers to defendants' . . . due to defendants' improper use of plaintiff's proprietary information would obviously create a lasting, irreparable harm").

83. Financial harm that cannot practically be remedied is irreparable harm. *T-Mobile USA, Inc. v. Chong*, 2014 U.S. Dist. LEXIS 47215 at *13 (W.D. Wash. Apr. 4, 2014). Even if there were a way to quantify Takeda's loss by the unauthorized disclosure of its trade secrets, and there is not, it is unlikely that a single individual plaintiff such as Mr. Connelly would be in a position to pay Takeda a judgment of millions of dollars in lost commercially confidential information. Thus, Takeda is left without a practical remedy, even if the damage could be quantified. Other courts have held that preliminary injunctions are

available when a money judgment is in danger of being made worthless. *See, e.g., Hilao v. Estate of Marcos*, 25 F.3d 1467, 1479 (9th Cir. 1994) (even where the ultimate relief sought is money damages, federal courts have found preliminary injunctions appropriate where it has been shown that the defendant intended to frustrate any judgment on the merits by transferring its assets out of the jurisdiction); *Tri-State Generation and Transmission Ass'n, Inc. v. Shoshone River Power, Inc.*, 805 F.2d 351, 355 (10th Cir. 1986) (preliminary injunction was warranted where irreparable harm would result from the inability to collect a money judgment). Takeda likely will be irreparably harmed if it is forced to litigate this case in the tribal court, because it will have no recourse from the void proceedings and from the unauthorized disclosure of its trade secret information.

The Balance of Hardships Favors Takeda

84. Forcing Takeda to defend a products liability in the tribal court, which plainly lacks jurisdiction, and which BIA found lacks valid or trained judges and court personnel, works a hardship on Takeda in terms of risks of loss of its confidential information as well as the expenses of a trial, which are unlikely to ever be recovered. Connelly is ill-positioned to reimburse Takeda for a waste of resources and lost trade secrets, so Takeda likely will never recover from the losses incurred in trying the case in tribal court.

85. Connelly, on the other hand, has multiple other venues where he could pursue his case in a court with proper jurisdiction. For example, he could bring suit in Montana state or federal courts or in the federal MDL court, or in the consolidated litigation in Illinois. His Texas-based lead lawyers are counsel in other lawsuits pending in the Illinois consolidated litigation, so this is a venue familiar and convenient to his counsel. Any of these other courts could provide him with a fair opportunity to pursue his claims. He is not burdened by being required to follow the path of litigants around the country in pursuing his claims in state or federal courts, which can legitimately exercise jurisdiction over his case. To the extent that Connelly claims hardship in having to re-file his lawsuit in another court, it is a hardship of his own making—he chose to sue in tribal court, when the law clearly did not give the tribal court jurisdiction to hear his case. *See Warner Bros. Entm't v. Global Asylum, Inc.*, 2012 U.S. Dist. LEXIS 185695 at *63 (C.D. Cal. Dec. 10, 2012) (a hardship of a party's own making carries little weight when the court considers this element of a requested injunction). Thus, the balance of hardship between Takeda and Connelly favors Takeda.

An Injunction is in the Public Interest

86. Finally, an injunction against Connelly pursuing his claims in the tribal court is in the public interest. There is no public interest forcing a party to defend against serious claims in a court that plainly lacks jurisdiction. No court in

the nation has ever allowed such a sweeping exercise of tribal court jurisdiction. Courts should strive to uphold the dignity and respect for the judicial system. Allowing the tribal court to try this case when it plainly lacks jurisdiction to do so invites disrespect for judicial proceedings, and undermines the confidence of the public in the integrity of the court system.

87. For all these reasons, Takeda can establish that 1) it is likely to succeed on the merits; 2) it is likely to suffer irreparable harm in the absence of preliminary relief; 3) the balance of equities tips in its favor; and 4) an injunction is in the public interest. Thus, Takeda is entitled to a preliminary injunction against Connelly proceeding further in the tribal court.

PRAYER

For these reasons, Takeda requests that the Court enter:

1. Declaratory judgment that the Blackfeet Tribal Court lacks subject matter to hear the case of *Victor Connelly v. Takeda Pharmaceuticals America, Inc.; Takeda Pharmaceuticals U.S.A., Inc., F/K/A Takeda Pharmaceuticals North America, Inc.; and Takeda Pharmaceutical Company Limited*, Tribal No. 2013 CA 140;

2. A preliminary and permanent injunction against Victor Connelly precluding him from prosecuting or maintaining the Blackfeet Tribal Court case entitled: *Victor Connelly v. Takeda Pharmaceuticals America, Inc.; Takeda*

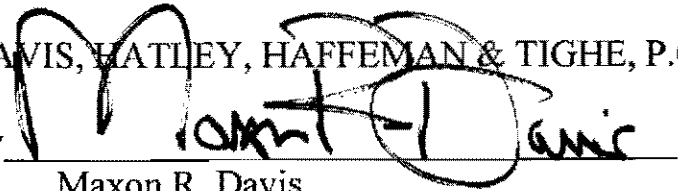
Pharmaceuticals U.S.A., Inc., F/K/A Takeda Pharmaceuticals North America, Inc.;
and Takeda Pharmaceutical Company Limited, Tribal No. 2013 CA 140, or from
filing or maintaining another suit against the Takeda defendants in the Blackfeet
Tribal Court arising from his use of Actos;

3. For costs and expenses incurred herein; and
4. For further necessary and proper relief as may seem just to the Court
and as to which Takeda is entitled.

DATED this 7th day of July, 2014.

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